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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: RONALD J. PETTIS, *et al.*

Confirmation No.: 4392

Serial No.: 10/028,989

Group Art Unit: 3763

Filed: December 28, 2001

Examiner: Williams, Catherine Serke

Attorney Docket No.: 11219-023-999
(500752 999022; P-4901P4)

Date: January 18, 2005

For: METHOD AND DEVICE FOR
REDUCING THERAPEUTIC DOSAGE

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.56 AND § 1.97

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references A01-A11, B01-B04 and C01-C58 listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." A copy of references C01, C05, C09, C20, C30, C32-C33, C35-C36, C42, C46, C48-C49 is submitted herewith.

This application is a continuation-in-part of U.S. application No. 09/893,746, filed June 29, 2001, which is a continuation-in-part of U.S. application No. 09/835,243, filed April 13, 2001, which is a continuation-in-part of U.S. application No. 09/606,909, filed June 29, 2000, which is a continuation-in-part of U.S. application no. 09/417,671, filed October 14, 1999. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed references A01-A11, B01-B04 and C02-C04, C06-C08, C10-C19, C21-C29, C31, C34, C37-C41, C43-C45, C47, C50-C58 have not been included herein as such copies are available in parent application No. 09/606,909, filed June 29, 2000. Applicants will provide copies of references A01-A11, B01-B04 and C02-C04, C06-C08, C10-C19, C21-C29, C31, C34, C37-C41, C43-C45, C47, C50-C58 upon request by the Examiner.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited".

Applicants respectfully request that the references be made of record in the file history of the application.

No fee is believed due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

by Jacqueline Bena
Reg No 43,492

Date: January 18, 2005

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LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.
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10/028,989

APPLICANT

Ronald J. Pettis, et al.

FILING DATE

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GROUP

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U.S. PATENT DOCUMENTS

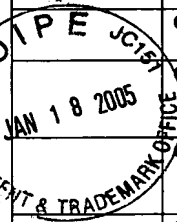
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,886,499	12-1989	Cirelli, et al.			
	A02	5,279,552	01-1994	Magnet			
	A03	5,582,591	12-1996	Cheikh			
	A04	5,800,420	09-1998	Gross, et al.			
	A05	5,848,990	12-1998	Cirelli, et al.			
	A06	6,007,821	12-1999	Srivastava, et al.			
	A07	6,056,716	05-2000	D'Antonio, et al.			
	A08	6,319,224	11-2001	Stout, et al.			
	A09	US 2002/0095134	07-2002	Pettis, et al.			
	A10	6,537,242	03-2003	Palmer, Phyllis J.			
	A11	US 2003/0073609	04-2003	Pinkerton			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	WO 94/23777	10-1994	PCT				
	B02	EP 0 429 842	08-1996	EP				
	B03	WO 97/21457	06-1997	PCT				
	B04	WO 00/09186	02-2000	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	"Flu vaccine: skin injection method effective in younger people," <i>American Health Line: Research Notes</i> (2004 Nov. 4)
C02	Agrawal, et al., Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in Mice, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 88, pp. 7595-7599, September 1991 Medical Sciences
C03	Autret, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, <i>Fundamental Clinical Pharmacology</i> , Vol. 3, No. 2, pp 170-171, 1989
C04	Bader M. Influenza vaccine experience in Seattle. <i>Am. J. Public Health</i> . 1980 May;70(5):545
C05	Belshe et al., "Serum antibody responses after intradermal vaccination against influenza," <i>New England Journal of Medicine</i> 351(22):2286-2294 (2004)
C06	Benoni, et al., Distribution of Ceftazidime in Ascitic Fluid, <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 25, No. 6, June 1984, pp. 760-763
C07	Bickers, et al., editors, <i>Clinical Pharmacology of Skin Disease</i> , pp. 57-90, Churchill Livingstone, Inc. 1984
C08	Bocci, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon a2 and Natural Interferon beta Administered Intradermally in Rabbits, <i>International Journal of Pharmaceutics</i> , 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)
C09	Branswell, "Vaccine stretching may be an option for future shortages, pandemics: studies," <i>Canadian Press News Wire</i> (2004 Nov. 3)
C10	Bronaugh RL, Stewart RF, Congdon ER. Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. <i>Toxicol. Appl. Pharmacol.</i> 1982 Mar 15;62(3):481-8.
C11	Brooks et al. Intradermal administration of bivalent and monovalent influenza vaccines. <i>Ann. Allergy</i> . 1977 Aug; 39(2):110-2



C12	Brown et al. The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults. <i>J. Infect. Dis.</i> 1977 Dec;136 Suppl:S466-71
C13	Callen, Intralesional Corticosteroids, <i>Journal of the American Academy of Dermatology</i> , University of Louisville School of Medicine, pp. 149-151, 1981
C14	Corbo M, Liu JC, Chien YW. Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. <i>Pharm Res.</i> 1989 Sep;6(9):753-8.
C15	Cossum, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, <i>The Journal of Pharmacology and Experimental Therapeutics</i> , pp. 1181-1190, Vol. 267, No. 3, 1993
C16	Cossum, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, <i>The Journal of Pharmacology and Experimental Therapeutics</i> , pp. 89-94, Vol. 269, No. 1, 1994
C17	Crooke, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts, <i>Clinical Pharmacology & Therapeutics</i> , pp. 641-646, Vol. 56, No. 6, Part 1, December 1994
C18	Crowe Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine. <i>Am. J. Med. Technol.</i> 1965 Nov-Dec;31(6):387-96
C19	Firooz, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, <i>Clinical and Experimental Dermatology</i> , Blackwell Science Ltd, September 1995
C20	Fjerstad, "U. Minnesota professor uses alternative flu vaccine technique," <i>FSView & Florida Flambeau via U-Wire</i> (2004 Nov. 15)
C21	Foy et al. Efficacy of intradermally administered A2 Hong Kong vaccine. <i>JAMA.</i> 1970 Jul 6;213(1):130
C22	Glenn et al. Advances in vaccine delivery: transcutaneous immunisation. <i>Exp. Opin. Invest. Drugs</i> 1999, 8(6):797-805
C23	Goodarzi, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, <i>Biopharmaceutics & Drug Disposition</i> , pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992
C24	Gramzinski et al. Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. <i>Mol. Med.</i> 1998 Feb;4(2):109-18
C25	Halperin et al. A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature. <i>Am. J. Public Health.</i> 1979 Dec;69(12):1247-50
C26	Haynes, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, <i>Anesthesiology</i> , Vol. 63, Vol. 5, pp. 490-499, Nov. 1985
C27	Herbert et al. Comparison of responses to influenza A/New Jersey/76-A/Victoria/75 virus vaccine administered intradermally or subcutaneously to adults with chronic respiratory disease. <i>J. Infect. Dis.</i> 1979 Aug;140(2):234-8
C28	Jakobson, et al., Variations in the Blood Concentration of 1,1,2-Trichloroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, <i>Acta Pharmacologica et Toxicologica</i> , November 1977
C29	Jarratt, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, <i>The Journal of Investigative Dermatology</i> , Vol. 62, No. 4, pp. 463-466, 1974
C30	Kenney et al., "Dose sparing with intradermal injection of influenza vaccine," <i>New England Journal of Medicine</i> 351(22):2295-2301 (2004)
C31	Kirkpatrick, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, <i>Anesthesiology</i> , September 1987
C32	Knox, "New research shows intradermal rather than intramuscular vaccine injection could stretch flu vaccine supplies," <i>National Public Radio: All Things Considered</i> (2004 Nov. 3)
C33	Kohn, "Flu shot technique yields more doses, studies find; critics say injecting skin rather than muscle is too difficult for common use," <i>The Baltimore Sun: Telegraph 3A</i> (2004 Nov. 4)
C34	Leroy, et al., Pharmacokinetics of Ceftazidime in Normal and Uremic Subjects, <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 25, No. 5, pp. 638-642, May 1984
C35	Majeski, "Alternative flu shot less effective in elderly; doctors proposed method to stretch vaccine supply," <i>Saint Paul Pioneer Press(Minnesota): Main 17A</i> (2004 Nov. 4)
C36	Majeski, "Technique could stretch vaccine; changing the way shots are given means the current supply of flu vaccine could immunize 10 times as many people, two Minnesota physicians say" <i>Saint Paul Pioneer Press(Minnesota): Main 1A</i> (2004 Oct. 27)
C37	Marian et al. 2001, <i>Acta Biologica Hungarica</i> , 52(1): 35-45
C38	McAllister et al., Solid and Hollow Microneedles for Transdermal Protein Delivery. <i>Proceed. Intl. Symp. Control. Rel. Bioact. Mater.</i> , 26 (Revised July 1999) <i>Controlled Release Society, Inc.</i> pp. 192-193
C39	McElroy et al. Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine. <i>N. Engl. J. Med.</i> 1969 Nov 6;281(19):1076
C40	McGugan, et al., Adrenal Suppression from Intradermal Triamcinolone. <i>The Journal of Investigative Dermatology</i> , Vol. 40, pp. 271-272, Baltimore, MD., 1963
C41	Merriam-Webster's Collegiate Dictionary, 10 th Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306
C42	Montagne et al., "Intradermal influenza vaccination - can less be more?" <i>New England Journal of Medicine</i> 351(22):2330-2332 (2004)
C43	Niculescu et al. Efficacy of an adsorbed trivalent split influenza vaccine administered by intradermal route. <i>Arch. Roum. Path. Exp. Microbiol.</i> 1981, 40(1):67-70

	C44	Payler DK. Intradermal influenza vaccine using Portojet 1976. Br. Med. J. 1977 Oct 29;2(6095):1152
	C45	Payler et al. Letter: Intradermal influenza vaccination. Br. Med. J. 1974 Jun 29;2(921):727
	C46	Rindfleisch, "La Crosse finding could curtail flu vaccine shortages," <i>Wisconsin State Journal</i> D9 (2004 Nov. 14)
	C47	Scott, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, British Medical Journal, April 25, 1981
	C48	Shute, "Second thoughts on the flu vaccine," <i>U.S. News & World Report</i> 137(17):80
	C49	Smith, "Low-dose vaccine helps block flu, study says younger adults seen benefiting," <i>The Boston Globe: National/Foreign A2</i> (2004 Nov. 4)
	C50	Supersaxo, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, <i>Pharmaceutical Research</i> , Vol. 5, No. 8, pp. 472-476, August 1998
	C51	Sutherest, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, <i>British Journal of Obstetrics and Gynecology</i> , May 1979
	C52	Sveinsson, 1939, Investigation on the Influence of Insulin and Adrenalin in Rabbits with Alimentary Fatty Liver and Muscles and on the Content of Fat and Sugar in Blood, Oslo, Norway (pp. 66-86)
	C53	Tauraso et al. Effect of dosage and route of inoculation upon antigenicity of inactivated influenza virus vaccine (Hong Kong strain) in man. <i>Bull. World Health Organ.</i> 1969;41(3):507-16
	C54	The American Heritage College Dictionary, 2000, 3 rd Edition; Houghton Mifflin Company, Boston, New York, p. 368
	C55	The Merck Manual of Diagnosis and Therapy, 1999, 17 th Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2559-2567
	C56	Ward, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, <i>British Journal of Dermatology</i> , August 1975
	C57	Wu, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, <i>Journal of Controlled Release</i> , July 1989
	C58	Zaynoun, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, <i>British Journal of Dermatology</i> , February 1973
EXAMINER		DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>		